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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,492	12/04/2001	Rango Dietrich	24826	6447

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NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/980,492	Applicant(s) DIETRICH ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15, 18-20, 33-44 and 50-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15, 18-20, 33-44 and 50-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114 and request for extension of time (2 months-granted), both filed 01/05/07 and the Amendment and Applicant's Arguments/Remarks filed 11/22/06 is acknowledged.

Claims 11-15, 18-20, 33-44 and 50-60 are pending in this action. Claims 11, 12 and 18 have been amended. Claims 1-10, 16, 17, 21-32 and 45-49 have been previously cancelled. Claims 11-15, 18-20, 33-44 and 50-60 are rejected.

Claim Rejections - 35 USC § 112

New Matter

Applicant's recitation of "*wherein the microsphere does not comprise an enteric coating*" in instant claims 11, 12 & 18 presents new matter since there is lack of support for this limitation in the present specification. While the limitation "*the acid-labile active compound does not have to be protected by an enteric coating*" is supported by the instant disclosure at page 3, first paragraph, the limitation "*wherein the microsphere does not comprise an enteric coating*" is not supported by the instant specification. Examiner requests clarification as to where in the instant specification support for the new limitation can be found.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-15, 18-20, 33-43 and 48-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inagi *et al.* (U.S. Patent No. 6,582,720 B1) in view of Benton *et al.* (U.S. Pat. No. 4,876,094).

The instant invention is drawn to an oral solid active compound unit comprising a microsphere, the microsphere comprising: a matrix comprising a mixture of at least one fatty alcohol and at least one solid paraffin; and an acid-labile active compound, selected from the group consisting of an acid-labile proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, wherein said acid-labile active compound is present in said matrix, and wherein the microsphere does not comprise an enteric coating.

The instant invention is also drawn to an oral solid active compound unit comprising a microsphere, the microsphere comprising: a matrix comprising a mixture of at least one fatty acid ester or at least one triglyceride, and at least one solid paraffin; and an acid-labile active compound, selected from the group consisting of an acid-labile proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, wherein said acid-labile active compound is present in said matrix and wherein the microsphere does not comprise an enteric coating.

Inagi et al. ('720) teach a gastric and/or duodenal pharmaceutical composition which comprises a medicament acting at the stomach and/or duodenum and one or more ingredients selected from water insoluble polymers, polyglycerin fatty acid esters, lipids and waxes (see column 1, line 53 – col. 2, line 9 and Abstract). *Inagi et al.* teach that the composition may be a matrix containing medicament, necessary additives and various water-insoluble ingredients as a mixture (col. 4, lines 60-67).

Suitable Polyglycerin fatty acid esters are disclosed at column 3, lines 14-32).

Lipids are disclosed and include higher fatty acids and salts thereof, higher alcohols and fatty acid glycerin esters and those of the wax include waxes and hydrocarbons (col. 3, lines 33-35). Examples of higher alcohols taught include stearyl alcohol and cetyl alcohol (col. 3, lines 35-39). Triglycerides are also disclosed (col. 3, lines 40-42). Waxes disclosed include paraffin wax (col. 3, lines 42-44). These ingredients, namely, water-insoluble polymers, polyglycerin fatty acid esters, lipids and waxes may be used singly or in combination (col. 3, lines 45-48).

Suitable medicaments disclosed include proton pump inhibitors (PPIs) such as omeprazole and lansoprazole, which can be used in amounts of 0.01 to 95% (col. 3, line 60 – col. 4, line 30). Moreover, with regards to amounts, it is deemed obvious to determine suitable

Art Unit: 1615

amounts through the use of routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art. Furthermore, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The particle size of the pharmaceutical composition is within a range of 30 to 300 μm (col. 5, lines 20-24).

Excipients are included and taught at column 4, lines 39-56.

A process for the preparation of a matrix is disclosed at col. 5, lines 39-50.

Inagi *et al.* do not teach a process that involves prilling a solution or dispersion to obtain drops.

Benton *et al.* ('094) teach a dual coated dosage formulation comprising dosage form cores such as matrix beads/microspheres containing a therapeutically active compound over which there are applied two unique coatings (see reference column 1, line 55 – col. 2, line 20). The controlled release microspheres/matrix beads can be prepared by microencapsulation processes including *prilling*, pan coating, granulation fluidization processes and other processes (col. 5, lines 60-66).

Ingestible materials taught include waxes such as paraffin, higher fatty acids, esters of fatty acids such as glyceryl tristearate, cetyl palmitate, diglycol stearate, glyceryl myristate,

Art Unit: 1615

triethylene glycol monostearate, higher fatty alcohols such as cetyl alcohol and stearyl alcohol and high molecular weight polyethylene glycols and mixtures thereof (col. 3, lines 23-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate processes, such as prilling, as taught by Benton *et al.* within the matrix formulations of Inagi *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Benton *et al.* teach a dosage formulation comprising micropsheres that are produced by effective microencapsulation processes, which include prilling. The expected result would be an improved and highly effective pharmaceutical composition for treating disorders and conditions.

Response to Arguments

Applicant's arguments with respect to claims 11-15, 18-20, 33-44 and 50-60 have been considered but are moot in view of the new ground(s) of rejection.

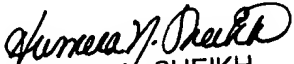
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


HUMERA M SHEIKH
PRIMARY EXAMINER

Art Unit 1615

March 19, 2007

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